

In re Appln. of Brechbiel et al.  
Application No. 10/767,133

### REMARKS

#### *The Present Invention*

The present invention is directed to  $^{225}\text{Ac}$ -HEHA compounds,  $^{225}\text{Ac}$ -HEHA compounds that are conjugated to targeting agents, methods of preparing  $^{225}\text{Ac}$ -HEHA compounds, and related methods of use.

#### *The Pending Claims*

Claims 1-15, 17-25, and 31-44 are currently pending. Claims 1-9 and 23-25 are directed to compounds, claims 10-15 are directed to methods of preparing compounds, claims 17-22 and 31-44 are directed to methods of use.

#### *Amendments to the Claims*

Claim 3 has been amended to make it more clear that the recited R groups are for compound (II). Claim 19 has been amended to correct an obvious typographical error. Claims 16 and 26-30 have been canceled. No new matter has been added by way of these amendments.

#### *Summary of the Office Action*

Claims 1, 3-9, 18, 23-25, 31, 32, and 36-44 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,696,551. Claims 16 and 26-30 have been rejected under 35 U.S.C. § 112, first paragraph. In addition, claims 16, 19, and 26-30 have been rejected under 35 U.S.C. § 112, second paragraph. Claims 17, 20, and 33-35 have been objected to as being dependent upon a rejected base claim. Claims 2, 10-15, and 21-22 have been indicated as allowable. Finally, the restriction requirement has been withdrawn. Reconsideration of the pending claims is hereby requested.

#### *Discussion of the Obviousness-Type Double Patenting Rejection*

Claims 1, 3-9, 18, 23-25, 31, 32, and 36-44 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-14 of U.S. Patent No. 6,696,551 ("the '551 patent"). The Office acknowledges that the claims of the subject application and the '551 patent are not identical, but contends that they are not patentably distinct. Applicants respectfully traverse the rejection for the following reasons (A-C).

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(A) Previous Restriction Requirement

The subject matter of the pending claims was part of originally presented claims in the application that later issued as the '551 patent. During prosecution of the '551 patent, a 48-way restriction requirement was issued. Applicants elected Group 2 for prosecution, which resulted in the claims of the '551 patent, which are directed to compound (I), wherein R is CO<sub>2</sub>H or CONHR'; and X is NO<sub>2</sub>, NH<sub>2</sub>, NCS, or NHC(O)CH<sub>2</sub>Z.

The rejection of the instant application is erroneous since the pending claims of the instant application cover subject matter non-elected in the earlier application in response to the restriction requirement. Accordingly, applicants respectfully request that the obviousness-type double patenting rejection be withdrawn.

(B) Non-Obviousness of Claimed Subject Matter

An obviousness-type double-patenting rejection over a patent is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the disclosure of the patent may not be used as prior art (see MPEP § 804). Therefore, the *claims* of the patent underlying the rejection must suggest the invention claimed in the subject application for the obviousness-type double patenting rejection to be proper. This is clearly not the case with respect to the '551 patent.

The Office contends that both the claims of the instant application and the '551 patent are directed to compounds encompassed by formula (II), wherein R is CO<sub>2</sub>H or CONHR'. Contrary to the Office's contention, Applicants note that the claims of the '551 patent are directed to compound (I), wherein R is CO<sub>2</sub>H or CONHR', and not to compound (I) wherein R is P(O)R'OH or P(O)(OR')OH or compound (II).

(i) Compound (II) Not Claimed in the '551 Patent

The pending claims are directed to subject matter previously non-elected in the application that issued as the '551 patent, namely, compound (I), wherein R is P(O)R'OH or P(O)(OR')OH and compound (II), wherein R is CO<sub>2</sub>H, CONHR', P(O)R'OH, or P(O)(OR')OH. One of ordinary skill in the art, upon reading the *claims* of the '551 patent, would not be motivated to arrive at the compounds of the present invention, since the *claims* of the '551 patent recite only compound (I) in which R is CO<sub>2</sub>H or CONHR'. Thus, the *claims* of the '551 patent do not recite compound (II) at all, which is structurally different from compound (I).

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(ii) Compound (I) of the '551 Patent is Different

Furthermore, while the pending claims include compound (I), R is different, *i.e.*, P(O)R'OH or P(O)(OR')OH. The *claims* of the '551 patent do not teach or suggest any phosphorus-based substituents for R, let alone P(O)R'OH or P(O)(OR')OH. P(O)R'OH and P(O)(OR')OH are not obvious variants of CO<sub>2</sub>H or CONHR'. Thus, it cannot be said that the *claims* of the '551 patent render claims 1, 3-9, 18, 23-25, 31, 32, and 36-44 obvious.

(C) Not All Claims Depend on Rejected Claims

Claims 3-4, 6-8, 18, 32, 39, 41, and 43 are dependent upon claim 1. Claims 5, 9, 23-25, 31, 36, 38, 40, 42, and 44 are dependent upon independent claim 2, which is not under rejection.

For the foregoing reasons, the obviousness-type double patenting rejection of claims 1, 3-9, 18, 23-25, 31, 32, and 36-44 is erroneous and should be withdrawn.

*Discussion of the Rejection under 35 U.S.C. § 112, first paragraph*

Claims 16 and 26-30 have been rejected under Section 112, first paragraph. According to the Office, the instant specification is enabling for treating cancer and tumors but does not provide enablement for treatment of all diseases.

To advance prosecution and not in acquiescence of the rejection, claims 16 and 26-30 have been canceled. Thus, this rejection has been rendered moot.

*Discussion of the Rejection under 35 U.S.C. § 112, second paragraph*

Claims 16, 19, and 26-30 have been rejected under Section 112, second paragraph, as allegedly indefinite. To advance prosecution and not in acquiescence of the rejection, claims 16 and 26-30 have been canceled.

Claim 19 has been amended to correct an obvious typographical error with regards to <sup>225</sup>Ac.

In view of the foregoing, it is submitted that the indefiniteness rejection has been obviated.

*Conclusion*

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

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Respectfully submitted,



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